# Vaccine Preventable Disease Program

# Yellow Fever Vaccine Program Manual

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# **Yellow Fever Certification**

According to International Health Regulations, yellow fever vaccine must be administered at certified yellow fever vaccination centers. Healthcare providers are authorized to administer the vaccine by state health departments and the states then report certified providers to the Centers for Disease Control and Prevention (CDC). The CDC maintains a registry of certified providers.

The New Jersey Department of Health (NJDOH), Vaccine Preventable Disease Program (VPDP) is responsible for managing the Yellow Fever Vaccine Program. Physicians licensed in New Jersey are permitted to apply for certification to participate in the program. Program participants are subject to the policies and procedures outlined in this document and the guidelines put forth by the CDC.

# **Certified Uniform Yellow Fever Stamp Holder**

A Certified Yellow Fever Stamp Holder, hereby referred to as the Uniform Stamp Holder, is the physician that is certified by the NJDOH VPDP to administer yellow fever vaccine to the public and participate in the Yellow Fever Vaccine Program. This person must designate at least one medical facility as a Yellow Fever Vaccination Center where persons may go to receive the yellow fever vaccine. The Uniform Stamp Holder is responsible for the activities of the designated facility with regard to the yellow fever vaccine.

# **Certified Yellow Fever Vaccine Uniform Stamp**

A Certified Yellow Fever Stamp, hereby referred to as the Uniform Stamp, is a stamp that contains a unique stamp number. This stamp is used by the designated Yellow Fever Vaccination Center(s) for international verification that a traveler has been vaccinated against yellow fever. This designation by NJDOH VPDP authorizes the center to administer yellow fever vaccine. Sanofi, the manufacturer of the vaccine, will only ship yellow fever vaccine to a designated Yellow Fever Vaccination Center

associated with an active Uniform Stamp Holder. Certification is required to order and administer yellow fever vaccine in the State of New Jersey.

# Who Can Apply?

Applicants must be a practicing physician who has a current New Jersey medical license and is in good standing with the New Jersey Board of Medical Examiners.

# **Application Requirements**

Applicants are encouraged to use the Uniform Stamp Application Checklist to ensure all application requirements are met. The following must be completed to apply for participation in the New Jersey Yellow Fever Vaccine Program:

- 1. Application/Renewal for Certified Yellow Fever Uniform Stamp.
- **2.** Acknowledgement of the Advisory Committee on Immunization Practices (ACIP) Recommendations and Vaccine Storage.

This form must be completed by the Uniform Stamp applicant as well as the Yellow Fever Coordinator at each designated Yellow Fever Vaccination Center.

# **3.** Completion of the CDC Yellow Fever Training Course and Transcripts with Scores.

The Uniform Stamp applicant, the Yellow Fever Coordinator, and any other staff with responsibilities associated with the administration of yellow fever vaccine must complete this course and the posttest. The Uniform Stamp applicant is responsible for ensuring that all appropriate staff take the course. The course is available through the CDC website at: http://www.cdc.gov/travel-training/?s\_cid=travelsite

The posttest is available at:

http://www.cdc.gov/travel-training/continuing-education.html

To take the tests, individuals must register with the CDC Training and Continuing Education Online at:

http://www2a.cdc.gov/TCEOnline/

The transcripts for each person must be submitted.

#### 4. Designation of Additional Vaccination Center(s) Form.

This form is to be completed by a Uniform Stamp Holder to designate additional facilities to administer yellow fever vaccine. The Uniform Stamp Holder is responsible for the activities of any designated facility with regard to the yellow fever vaccine.

5. New Jersey Immunization Information System (NJIIS).

The Uniform Stamp Holder must enroll as a user in NJIIS and ensure that all administered vaccines are entered into the system. The Uniform Stamp Holder is responsible for ensuring that all NJIIS requirements are met. For enrollment information, please see the NJIIS website at <a href="https://njiis.nj.gov/njiis/">https://njiis.nj.gov/njiis/</a>

#### 6. Sanofi Pasteur New Customer Form.

Approval of providers for the Yellow Fever Vaccine Program is at the discretion of the NJDOH VPDP. After the application has been approved the NJDOH VPDP will order a Uniform Stamp to be sent to the Uniform Stamp Holder and issue a certification letter with expiration date. Forms are available on the Yellow Fever Program webpage at: <a href="http://nj.gov/health/cd/topics/yfever.shtml">http://nj.gov/health/cd/topics/yfever.shtml</a>.

# **Responsibilities of Uniform Stamp Holder**

A Yellow Fever Vaccination Center is approved by the NJDOH VPDP; the Uniform Stamp Holder is responsible for the stamp and for ensuring the site is in compliance with the program requirements. Any time a Uniform Stamp Holder is no longer associated with a Yellow Fever Vaccination Center, the designation is no longer valid. The Uniform Stamp Holder must notify the NJDOH VPDP of any changes to the information on record for the Uniform Stamp Holder or any designated Yellow Fever Vaccination Center.

A Uniform Stamp Holder can be responsible for more than one Yellow Fever Vaccination Center. The Uniform Stamp Holder must complete the Designation of Additional Vaccination Center Form, available on the Yellow Fever Program webpage at: <a href="http://nj.gov/health/cd/topics/yfever.shtml">http://nj.gov/health/cd/topics/yfever.shtml</a>, and must designate a medically trained staff member for each site to serve as the Yellow Fever Vaccine Coordinator. The Yellow Fever Vaccine Coordinator must be an individual who is licensed by a health-related board within New Jersey and whose scope of practice includes vaccination (i.e., physician, nurse, pharmacist, or physician's assistant). A change of the Yellow Fever Vaccine Coordinator must be reported to the NJDOH. The Uniform Stamp Holder may also serve as the Yellow Fever Vaccine Coordinator for up to two designated Yellow Fever Vaccination Centers. Yellow Fever Vaccine Coordinators who are not also the Uniform Stamp Holder may serve as the Coordinator for only one designated Yellow Fever Vaccination Center.

Staff at a designated Yellow Fever Vaccination Center is expected to be familiar with yellow fever vaccine administration standards, as well as the recommended recordkeeping and storage procedures that are outlined in the CDC Yellow Fever Vaccine Course. The Uniform Stamp Holder is responsible for ensuring that the site is in compliance with CDC Vaccine Storage and Handling Toolkit available at <a href="http://www.cdc.gov/vaccines/recs/storage/toolkit/">http://www.cdc.gov/vaccines/recs/storage/toolkit/</a>.

The NJDOH VPDP may revoke a center's designation or a Uniform Stamp Holder's certification if the center does not conform to the conditions of the program or if the

Uniform Stamp Holder fails to renew his/her certification according to the guidelines. Facilities that lose their designation will be removed from the CDC central registry of Yellow Fever Vaccination Centers.

#### **Period of Certification/Recertification**

Uniform Stamp Holders must apply for recertification every three (3) years and complete the Application/Renewal for Certified Yellow Fever Uniform Stamp Form, available on the Yellow Fever Program webpage at: <a href="http://nj.gov/health/cd/topics/yfever.shtml">http://nj.gov/health/cd/topics/yfever.shtml</a>. Uniform Stamp Holders must complete and submit this form by December 31 of the expiration year indicated on the certification letter. Failure to submit the form will result in the removal of the Uniform Stamp Holder and/or designated Yellow Fever Vaccination Center from the list of providers able to purchase yellow fever vaccine from Sanofi. Approval for renewal in the Yellow Fever Vaccine Program is at the discretion of the NJDOH VPDP.

# Responsibilities of Yellow Fever Vaccine Coordinator

The Yellow Fever Vaccine Coordinator must be an individual who is licensed by a health-related board within New Jersey and whose scope of practice includes vaccination (i.e., physician, nurse, pharmacist or physician's assistant). This person is responsible for ensuring that the site is in compliance with all requirements under the direction of the Uniform Stamp Holder. Responsibilities are listed under the "Standards, Recordkeeping, and Storage" section, and include but are not limited to, ensuring the following activities occur: proper storage and handling of vaccine, completion of online CDC training for all pertinent staff, maintaining required documentation and records (i.e. Standing Orders, Vaccine Management Plan, Temperature Logs, transcripts for CDC Yellow Fever Vaccine Course). The Yellow Fever Vaccine Coordinator also serves as the contact person for the Yellow Fever Vaccination Center and the NJDOH VPDP.

The Uniform Stamp Holder may also serve as the Yellow Fever Vaccine Coordinator at no more than two designated Yellow Fever Vaccination Centers. Yellow Fever Vaccine Coordinators who are not also the Uniform Stamp Holder may serve as the Coordinator for only one designated Yellow Fever Vaccination Center. A change of the Yellow Fever Vaccine Coordinator must be reported to the NJDOH VPDP.

# Registries

After a Uniform Stamp Holder is certified and has designated a Yellow Fever Vaccination Center, the VPDP will provide the centers information to the CDC to be posted on their website. These registries facilitate the ability of persons to locate Yellow Fever Vaccination Centers in their area. Uniform Stamp Holders should review the information on the registry to ensure that accurate information is posted.

The registry is available at: <a href="http://wwwnc.cdc.gov/travel/yellow-fever-vaccination-clinics/search">http://wwwnc.cdc.gov/travel/yellow-fever-vaccination-clinics/search</a>

# **Change Notifications**

Certification or designation to administer yellow fever vaccine cannot be transferred from person to person or from site to site. Any change to the information on record with the VPDP must be reported immediately using the **Change Notification** form, available on the Yellow Fever Program webpage at: <a href="http://nj.gov/health/cd/topics/yfever.shtml">http://nj.gov/health/cd/topics/yfever.shtml</a>. Failure to submit the **Change Notification** form could inhibit the ability to order vaccine and/or remain in the Yellow Fever Vaccine Program. This form must be signed by the Uniform Stamp Holder in order to be processed. The information will be updated accordingly on the CDC website and with Sanofi.

#### • Uniform Stamp Holder

Any contact changes for the Uniform Stamp Holder must be reported immediately. If the Uniform Stamp Holder is no longer associated with a Yellow Fever Vaccination Center, the designation is no longer valid. The center must immediately cease the administration of the yellow fever vaccine.

#### Yellow Fever Vaccine Coordinators

The Yellow Fever Vaccine Coordinator must be an individual who is licensed by a health-related board within New Jersey and whose scope of practice includes vaccination (i.e., physician, nurse, pharmacist, or physician's assistant). The Uniform Stamp Holder may serve as the Yellow Fever Vaccine Coordinator, if the Uniform Stamp Holder is associated with no more than two Vaccination Centers. A change of the Yellow Fever Vaccine Coordinator must be reported to the NJ DOH.

#### Vaccine Shipping Address Changes

Please submit the **Change Notification** for prior to an address change at any of the designated Yellow Fever Vaccination Centers to ensure vaccine is delivered to the appropriate site.

# **Replacement Stamp**

Uniform Stamps may be replaced if they are lost or damaged. Uniform Stamp Holders may request a replacement stamp by contacting the VPDP. The VPDP will order a new stamp. If the stamp was damaged, please return it along with the request. If a lost stamp is found after a replacement is ordered, please notify the VPDP.

### Standards, Recordkeeping, and Storage

Yellow Fever Vaccination Centers must conform to acceptable standards and must adhere to the manufacturer's instructions, ACIP guidelines, and VPDP requirements. Yellow Fever Vaccination Centers may be audited by the VPDP. Failure to provide any required documentation upon request may result in the inability to order vaccine or the cancellation of the Uniform Stamp and designation of the Yellow Fever Vaccination Centers associated with the stamp.

#### Vaccine Storage

The Uniform Stamp Holder is ultimately responsible for the safe storage of the vaccine in conjunction with the Yellow Fever Vaccine Coordinator. See the CDC Vaccine Storage and Handling website for recommendations and guidance: <a href="http://www.cdc.gov/vaccines/recs/storage/default.htm">http://www.cdc.gov/vaccines/recs/storage/default.htm</a>

#### Standing Orders

All Yellow Fever Vaccination Centers are required to develop Standing Orders for Administering Yellow Fever Vaccine, which must be signed by the Uniform Stamp Holder and kept at the Designated Vaccination Center.

#### • Vaccine Management Plan

All Yellow Fever Vaccination Centers are required to develop a Vaccine Management Plan for the storage and handling of the yellow fever vaccine. This Management Plan should include guidelines for emergencies such as power outages to ensure the vaccine remains at proper temperature. The Vaccine Management Plan should be kept at the Designated Vaccination Center.

#### • Temperature Logs

All Yellow Fever Vaccination Centers are required to maintain an up to date vaccine temperature log for each storage unit containing yellow fever vaccine. Temperatures should be recorded twice daily with any temperature excursions reported to Sanofi for assistance with determining vaccine viability.

#### • Reporting of Adverse Events

Providers should report all suspected adverse events after vaccine administration to the Vaccine Adverse Event Reporting System available through <a href="https://vaers.hhs.gov/index">https://vaers.hhs.gov/index</a>. Healthcare providers should also report these events to the manufacturer.

#### • Training/Education

Uniform Stamp Holders, the Yellow Fever Vaccine Coordinator, and any staff with responsibilities associated with the administration of yellow fever vaccine must complete the CDC Yellow Fever Vaccine Course. Following completion of the course, all individuals are required to complete the evaluation and test, print the transcript with scores, and submit the transcript to the Yellow Fever Vaccine Program. The course is available through the CDC website at:

http://www.cdc.gov/travel-training/?s\_cid=travelsite

The posttest is available at:

http://www.cdc.gov/travel-training/continuing-education.html

To take the tests, individuals must register with the CDC Training and Continuing Education Online at: http://www2a.cdc.gov/TCEOnline/

The transcripts for each person must be submitted.

#### Vaccine Information Statement (VIS)

As required by the National Childhood Vaccine Injury Act of 1986, all Yellow Fever Vaccination Centers are required to provide persons with the most recent version of the VIS for yellow fever prior to vaccine administration. The VIS provides information about the risks and benefits of the vaccine.

#### New Jersey Immunization Information System (NJIIS)

The Uniform Stamp Holder must enroll as a user in NJIIS and ensure that all administered vaccines are entered into the system. The Uniform Stamp Holder is responsible for ensuring that all NJIIS requirements are met. For enrollment information, please see the NJIIS website at <a href="https://njiis.nj.gov/njiis/">https://njiis.nj.gov/njiis/</a>

• International Certificate of Vaccination (ICV) or Prophylaxis Card
Each Yellow Fever Vaccination Center must have ICV cards to distribute
to patients that receive the yellow fever vaccine. The cards can be
purchased through the United States Government Bookstore. The website
is available at http://bookstore.gpo.gov/products/sku/017-001-00566-5

#### • Certification Letter

Each Yellow Fever Vaccination Center must retain the certification letter issued by NJ DOH VPDP as proof of certification until the expiration date indicated on the letter.